DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

November 9, 2001

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

WARNING LETTER

Mr. Alexander Goldring, President
Neptune Manufacturing, Inc.
5429 1/2 West Pico Boulevard
Los Angeles, California 90019

WL-07-02

Dear Mr. Goldring:

We inspected your firm, located at the above address on July 12 and 13, 2001 and found that you have serious deviations from the Seafood HACCP regulations (21 CFR Part 123). These deviations cause the hot and cold smoked vacuum packaged refrigerated fishery products, pickled herring and pickled mackerel processed by your firm to be in violation of section 402 (a)(4) of the Federal Food, Drug, and Cosmetic Act. You can find this Act and the seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations were as follows:

1. You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for pickled herring and pickled mackerel to control the food safety hazards of histamine formation and pathogen growth and survival. A similar deviation was encountered during our inspection on May 25 through June 1, 2000. During that inspection, our investigator found that your firm had no written HACCP plans for the hot & cold smoked fishery products that you were manufacturing at the time. As such, you should be aware that all fish and fishery products require HACCP plans when there is a food safety hazard that is reasonably likely to occur.

2. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6(c)(3). However, your firm's HACCP plan for hot smoked mackerel lists a critical limit, [redacted], at the brining critical control point that is not adequate to control the food safety hazard histamine formation.

3. You must implement the monitoring procedures listed in your HACCP plan, to comply with 21 CFR 123.6(b). However your firm did not follow the monitoring procedures of:

   (a) minimum 2:1 brine ratio of brine to fish, and maximum fish thickness of 1½ inches at the brining critical control point to control the food safety hazard *Clostridium botulinum*

toxin formation in the finished product listed in your HACCP plans for hot and cold smoked vacuum packaged refrigerated fishery products.

(b) monitoring the cold smoking temperature every 1-2 hours during the process at the cold smoking critical control point to control the food safety hazard pathogen growth in your cold smoked vacuum packaged refrigerated fishery products.

(c) monitoring thermocouple probes in the three thickest fish in the coldest part of the smoker and continuously monitoring the temperature at the smoking critical control point for your hot smoked products. Specifically, you cannot carry out this procedure since you do not have the equipment (i.e. temperature probes or a continuous temperature recording device) to perform the monitoring.

4. You must have a HACCP plan that lists the critical limits that must be met, to comply with 21 CFR 123.6 (c) (3). However your firm's HACCP plan for hot smoked mackerel lists a critical limit, [redacted], at the cooler storage critical control point that is not adequate to control the food safety hazards histamine formation or *Clostridium botulinum* toxin formation. FDA recommends the storage temperature of vacuum packaged refrigerated products and scombroid species should not exceed 40° F.

5. You must implement the record keeping system listed in your HACCP plan, to comply with 21 CFR 123.6(b). However, your firm did not record monitoring observations at any critical control point to control the food safety hazards histamine formation, *Clostridium botulinum* toxin formation, or pathogens listed in your HACCP plans for hot smoked vacuum packaged refrigerated fish or cold smoked vacuum packaged refrigerated fish. Specifically you could not provide any monitoring records for June or July 2001. In addition, processing and other information must be recorded at the time it is observed.

6. You must adequately monitor sanitation conditions and practices during processing, to comply with 21 CFR 123.11(b). However, your firm did not monitor the following areas with sufficient frequency to ensure control:

   (a) **Safety of the water** as evidenced by a hose in the brining room that lacked a back flow prevention device.

   (b) **The condition and cleanliness of food contact surfaces** as evidenced by fish debris on the meat slicer, weighing finished product on a balance not cleaned and sanitized prior to use.

   (c) **Prevention of cross contamination from insanitary objects to food** as evidenced by using a wooden pole to mix the brine solution, packing finished ready-to-eat smoked fish into unlined boxes previously used to hold raw materials, storing in-process fish in dirty open weave trays, using a tub that had been on the floor to keep fish submerged in the brine tank, an employee using finished product (a smoked fish) to part a dirty strip curtain, employees handling finished product without cleaning and sanitizing their hands.

Similar deviations were encountered during our inspection on May 25 through June 1, 2000. The investigator observed that you failed to monitor and document sanitation conditions and practices as required by the seafood HACCP regulation. Sanitation deficiencies were also observed during that inspection; products requiring refrigeration were observed being stored at inappropriate temperatures, and your sanitizer strength was not adequate in that it was prepared at an inappropriate concentration.

7. If you import fish or fishery products into the United States, you must maintain an affirmative step asserting that the fish or fishery products have been handled or processed in accordance with the seafood HACCP regulations, to comply with 21 CFR 123.12(a)(2)(ii). However, you firm could not provide an adequate affirmative step for (a) herring imported from [redacted] and (b) mackerel imported from [redacted] Specifically, the firm's certificates for the herring suppliers do not reference the U.S. seafood HACCP regulations, and the certificate obtained for the imported mackerel for Agnefest Seafood, Lyngdol, Norway is expired.

8. You must maintain product specifications for fish or fishery products that you import into the United States, to comply with 21 CFR 123.12(a)(2)(i). These product specifications should be designed to identify all of the potential food safety hazards associated with the fish or fishery product that are reasonably likely to occur. However, your firm does not have any product specifications for herring and/or mackerel that you have imported into the United States.

We may take further action if you do not promptly correct these violations. For instance, we may take further action to seize your product(s) and/or enjoin your firm from operating. With respect to your imported products, failure to comply can cause these products to be denied entry into the United States per Section 801 of the Act, or to be subject to detention without physical examination.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response documentation such as HACCP plans, monitoring forms and recent monitoring data or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Your written reply should be addressed to:

Thomas L. Sawyer, Director, Compliance Branch
U. S. Food and Drug Administration
19900 MacArthur Boulevard, Suite 300
Irvine, California 92612-2445

If you have questions regarding any issue in this letter, please contact Robert B. McNab, Compliance Officer at (949) 798-7709.

Sincerely,

Alonza E. Cruse
District Director